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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,602	02/22/2005	John Hadden	3115.00066	4753

48924 7590 06/29/2010

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EXAMINER	
JUEDES, AMY E	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
06/29/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,602	HADDEN ET AL.	
	Examiner	Art Unit	
	AMY E. JUEDES	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/12/10*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment and remarks, filed 4/12/10, are acknowledged.

Claim 24 has been amended.

Claim 24 is pending and is under examination.

2. The objection to claim 24 is withdrawn in view of Applicant's amendment to the claim.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 24 stands rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,614,504, March 25, 1997.

As set forth previously, The '504 patent teaches a method of enhancing the immune response to a vaccine comprising administering an adjuvant formulation comprising inosine 5-monophosphate compounds, including MIMP (i.e. a protected IMP compound, see column 1, 6, 9, and, in particular). The '504 patent teaches administering the IMP compounds to treat influenza (see column 14, in particular). The '504 patent teaches measuring a response to the vaccine by performing proliferation assays in response to viral antigen (i.e. detecting a T cell response, see column 17, in particular). The '504 patent also teaches measuring an enhanced DTH response and T cell activation and cytokine secretion in response to IMP compounds (i.e. detecting a T cell response, see column 18-19, in particular).

Applicant's arguments filed 4/12/10 have been fully considered, but they are not persuasive.

Applicant argues that that the '504 patent does not teach administering the IMP compound in combination with an agent, as recited in the amended claims. Applicant particularly argues that the administration of squalene in combination with MIMP for treating influenza, as taught by the '504 patent, does not anticipate the instant claim

since squalene is merely an excipient.

Squalene is used in vaccines as a part of an adjuvant formulation, and can be considered a “vaccine agent” as recited in the instant claims. Furthermore, the ‘504 patent also teaches other embodiments, such as administering MIMP in combination with any commercially available vaccine for treating viral infection, including influenza virus (see columns 12, 14 and 16, in particular). Said vaccine for treating influenza virus can also be considered an "antiviral agent", a "microbial agent", or a "vaccine agent", as recited in the instant claims.

Applicant further argues that the '504 patent describes only a general T cell stimulation, and does not show a T cell response in influenza. Applicant concludes that without showing that IMP provides a T cell response specifically to influenza, the ‘504 patent does not disclose the method of the present invention.

As an initial matter, it is noted that the instant claim is not limited to detecting an influenza specific T cell response but merely requires detecting any T cell response. The ‘504 patent teaches multiple modes of detecting T cell response for treatment of viral infections such as influenza. For example, the ‘504 patent teaches that the IMP compounds stimulate T cells, and that patients for treatment can be selected by evaluating the ability of the compounds to stimulate T cells to ensure that only patients in which T cell stimulation is detected are selected fro treatment (see column 11, last paragraph, column 14, and column 27, in particular). Thus, the ‘504 patent teaches detecting T lymphocyte responses before treatment with the IMP compound, which is encompassed by the instant claims which merely require detecting a T cell response (i.e. before or after administration of the IMP compound). Furthermore, the ‘504 patent also teaches that after administration of viral vaccine combined with IMP compound, proliferation assays in response to viral antigen can be performed in order to determine if the subject has been successfully immunized (see column 17, 5th full paragraph). It is well established that proliferation assays in response to viral antigen are performed to measure T cell responses.

4. No claim is allowed.

5. **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, whose telephone number is 571-272-4471. The examiner can normally be reached on 8am to 4:30pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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